

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC., a Delaware corporation,

Plaintiff,

V.

DEXCOM, INC., a Delaware corporation,

Defendant.

C.A. No. _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Abbott Diabetes Care, Inc., by and through its undersigned attorneys,
complaints as follows:

Nature of Action

1. This is an action for patent infringement under 35 U.S.C. § 271 involving United States Patent Nos. 6,175,752 (the “752 patent”), 6,284,478 (the “478 patent”), 6,329,161 (the “161 patent”) and 6,565,509 (the “509 patent”) (collectively referred to as “Abbott patents”), which relate to glucose monitoring devices, systems, and methods.

Jurisdiction and Venue

2. Jurisdiction for this action is based on 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

3. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

4. This Court has personal jurisdiction over the Defendant because, among other things, it is organized under the laws of Delaware.

Parties

5. Abbott Diabetes Care, Inc. (“Abbott”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Alameda, California.

6. DexCom, Inc. (“DexCom”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in San Diego, California.

Background

7. Abbott owns the four patents listed in paragraph 1, which cover medical devices, systems, and methods for monitoring glucose levels in humans.

8. On January 16, 2001, the United States Patent and Trademark Office (“PTO”) duly and legally issued the ‘752 patent, which is entitled “Analyte Monitoring Device and Methods of Use.” Abbott (formally “Therasense, Inc.”) is the assignee and owner of the ‘752 patent and accordingly has the right to sue for infringement. A true and correct copy of the ‘752 patent is attached hereto as Exhibit A.

9. On September 4, 2001, the United States Patent and Trademark Office (“PTO”) duly and legally issued the ‘478 patent, which is entitled “Subcutaneous Glucose Electrode.” Abbott is the assignee and owner of the ‘478 patent and accordingly has the right to sue for infringement. A true and correct copy of the ‘478 patent is attached hereto as Exhibit B.

10. On December 11, 2001, the United States Patent and Trademark Office (“PTO”) duly and legally issued the ‘161 patent, which is entitled “Subcutaneous Glucose Electrode.” Abbott is the assignee and owner of the ‘161 patent and accordingly has the right to sue for infringement. A true and correct copy of the ‘161 patent is attached hereto as Exhibit C.

11. On May 20, 2003, the United States Patent and Trademark Office (“PTO”) duly and legally issued the ‘509 patent, which is entitled “Analyte Monitoring Device and

Methods of Use.” Abbott is the assignee and owner of the ‘509 patent and accordingly has the right to sue for infringement. A true and correct copy of the ‘509 patent is attached hereto as Exhibit D.

12. DexCom intends to market the DexCom™ STS™ Continuous Glucose Monitoring System. Pursuant to its plans to market its product, DexCom filed a PMA (premarket approval) application in March 2005 with the FDA seeking approval to sell its product in the United States. After submitting its PMA with the FDA, DexCom sought and obtained agreement from the FDA in May 2005 to expedite review of its application.

13. DexCom is well into the FDA-approval process, and has invested millions of dollars into the process of obtaining FDA approval to market its product. For example, according to its website, DexCom has already conducted all the clinical trials necessary for approval and, after reviewing the PMA, the FDA not ask DexCom to conduct any additional clinical studies.

14. In addition, DexCom recently passed two key inspections by the FDA. When asked about the significance of these inspections, Andy Rasdal, the CEO of DexCom, announced that:

“Successfully completing BIMO and QSR inspections is a very significant achievement for DexCom as we progress toward being a commercial enterprise capable of launching a product, especially as the inspections occurred earlier than we would have expected, only four months after filing our first-ever PMA. Since we filed our PMA application, we have continued to have a very interactive, timely and productive review process with the FDA.”

<http://www.shareholder.com/dexcom/ReleaseDetail.cfm?ReleaseID=170231>.

15. DexCom has publicly stated that it expects FDA approval for marketing by the second quarter of 2006, and has repeatedly assured the marketplace that the FDA-approval process is going smoothly.

16. In addition to filing its PMA with the FDA, DexCom has attended at least two trade shows where it has publicized and displayed its product.

17. Upon information and belief, the products displayed at the trade shows were manufactured for the purpose of showcasing at the trade shows rather than for the purpose of gathering information for submission to the FDA.

18. DexCom has been aware of the Abbott patents for a long time and, despite that fact, has continued to develop its product, has continued to promote its product, and has continued to take steps to commercially launch its product.

19. On August 1, 2005, Abbott sent DexCom a letter concerning Abbott patents, and advised DexCom that it will take every reasonable step to enforce those patents. DexCom has not, however, changed its course by withdrawing its PMA application, altering the design of its infringing product, or suggesting that it was willing even to consider those steps. On the contrary, after being sent the letter, DexCom attended a trade show in Washington D.C. to continue to promote its product. Thus, DexCom has demonstrated its continuing intent to market its product despite knowing of Abbott's patents and despite Abbott's notification letter making it clear that it would file a lawsuit to protect its patent rights.

COUNT I

Declaration of Patent Infringement

20. Abbott re-alleges and incorporates herein the allegations of paragraphs 1 through 19.

21. There is an actual, substantial, continuing justiciable controversy between Abbott and DexCom regarding whether DexCom will infringe the Abbott patents.

22. DexCom is making meaningful preparations for and/or engaging in activity directed toward making, selling, offering to sell, and using the DexCom™ STS™ Continuous Glucose Monitoring System, which will infringe the Abbott patents as soon as DexCom begins marketing. For example, DexCom has invested millions of dollars into obtaining FDA approval to market its product, has run extensive clinical trials, and has also advertised its product at trade shows.

23. DexCom also has refused to change course despite being well aware of Abbott's patents.

24. When DexCom receives FDA approval, DexCom's product and its methods of use will infringe one or more claims of each of Abbott's patents.

25. Therefore, Abbott is entitled to declaratory relief in the form of a judicial declaration that DexCom's product will infringe one or more claims of each of Abbott's patents.

COUNT II

Patent Infringement In Connection With Trade Shows

26. Abbott re-alleges and incorporates herein the allegations of paragraphs 1 through 19.

27. DexCom's product infringes one or more claims of Abbott's patents.

28. DexCom's manufacture of its product for the purpose of showcasing it at trade shows constitutes an infringing act, not exempted by 35 U.S.C § 271(e)(1) relating to the collection of information for submission to the FDA. Thus, Dexcom has infringed Abbott's patents.

Relief Requested

WHEREFORE, Plaintiff Abbott Diabetes Care, Inc. prays that the Court enter judgment against Defendant DexCom, Inc. and in favor of Abbott Diabetes Care, Inc. as follows:

- A. For a finding that DexCom's product infringes one or more claims of Abbott's patents;
- B. For a declaration that DexCom's product will infringe one or more claims of Abbott's patents when it receives FDA approval of its PMA application;
- C. For an award of costs; and
- D. For such other relief as the Court determines to be just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL

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